

(c) If a registrant possesses information required to be submitted by paragraph (a)(2) of this section, the information must be submitted in accordance with any schedule contained in the Agency's request for the information.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998, as amended at 63 FR 41193, Aug. 3, 1998]

§ 159.160 Obligations of former registrants.

(a) *General.* A former registrant is obliged to continue to submit information concerning the registration of a pesticide product previously held by the registrant and otherwise reportable under the provisions of this part for a period of 5 years after the registration of the pesticide product has been canceled or transferred to another registrant, with the exceptions provided by paragraph (b) of this section.

(b) *Exceptions.* Notwithstanding the provisions of paragraph (a) of this section, a former registrant is not obligated to report information pursuant to this part if any of the following conditions are applicable:

(1) The information is first obtained by the person more than 1 year after the date on which the person ceased to hold the registration of the product to which the information pertains, and the person holds no active pesticide registrations, or for some other reason cannot reasonably be expected to receive information concerning the formerly registered product.

(2) The information is associated solely with an inert ingredient, contaminant, impurity, metabolite, or degradate contained in a product, and the information is first obtained by the person more than 1 year after the date upon which the person ceased to hold the registration of the product.

(3) The information is associated with an active ingredient or a formerly registered product, and the active ingredient or every active ingredient contained in the formerly registered product has not been contained in any pesticide product registered in the United States for any part of the 3-year period preceding the date on which the person first obtained the information.

(4) The information pertains solely to a formerly registered product that no longer meets the definition of "pesticide" in section 2(u) of FIFRA.

(c) *Information arising from litigation.* Notwithstanding any other provisions of this section, a former registrant is obliged to submit information otherwise reportable under this part concerning formerly-registered pesticide products which arises in the course of litigation concerning the effects of such products, regardless of when the information is first acquired, provided that neither of the provisions of paragraphs (b)(3) or (b)(4) of this section are met. Such information shall be submitted in the same manner and according to the same schedules as it would have to be submitted by a current registrant of a pesticide product to which the information pertained.

[62 FR 49388, Sept. 19, 1997; 63 FR 33582, June 19, 1998, as amended at 73 FR 75596, Dec. 12, 2008]

§ 159.165 Toxicological and ecological studies.

Adverse effects information must be submitted as follows:

(a) *Toxicological studies.* (1) The results of a study of the toxicity of a pesticide to humans or other non-target domestic organisms if, relative to all previously submitted studies, they show an adverse effect under any of the following conditions:

(i) That is in a different organ or tissue of the test organism.

(ii) At a lower dosage, or after a shorter exposure period, or after a shorter latency period.

(iii) At a higher incidence or frequency.

(iv) In a different species, strain, sex, or generation of test organism.

(v) By a different route of exposure.

(2) Acute oral, acute dermal, acute inhalation or skin and eye irritation studies in which the only change in toxicity is a numerical decrease in the median lethal dose (LD₅₀), median lethal concentration (LC₅₀) or irritation indices, are not reportable under this part unless the results indicate a more restrictive toxicity category for labeling under the criteria of 40 CFR 156.62.

(b) *Ecological studies.* The results of a study of the toxicity of a pesticide to